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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,834	01/25/2006	Kimoon Kim	1751-396	7491

6449 7590 01/18/2008

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
SAMALA, JAGADISHWAR RAO	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
01/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,834	KIM ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of the amendment filed on 11/13/2007. Upon entering the amendment, claims 6 and 7 are amended and claim 5 is cancelled. The pending claims 1-4 and 6-7 are presented for examination.

Response to Arguments

2. Applicant's arguments filed on 11/13/2007 with respect to claims under 35 U.S.C. 103(a) have been fully considered but they are not persuasive. The 112(1) rejection for claims 5-7 is withdrawn. The 103(a) rejection is maintained and made **FINAL**.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO 03/055888 A1) in view of Pun et al. (US 2003/0008818 A1).

Kim discloses the preparation of hydroxycucurbituril derivatives as recited in claim 1. And hydroxycucurbituril and their derivatives can include various compounds with different sizes, and have Lewis base atoms near the cavities of the molecule, which can form complex with various organic compounds, and thus the cucurbituril derivatives can have a wide range of applications. And further, cucurbituril derivatives can be used as additives to polymers, cosmetics, drugs and food, and used as drug carriers (see page 17 and 18).

Kim meets the limitations as described above but fails to include biodegradable polymers such as PGLA, PEG, cellulose derivatives, albumin, gelatin, alginate therein. However, it would have been obvious to one of ordinary skill in the art at the time of invention was made to incorporate additional biodegradable polymers such as PGLA, PEG, cellulose derivatives, albumin, gelatin, alginate to increase the therapeutic efficacy when Kim is taken in view of Pun teaches a composition containing particulate composite of a polymer and a therapeutic agent, and the composition can be used to treat carious disorders.

Pun discloses a composition containing particulate composite of a biodegradable polymer (PEG) and a therapeutic agent and a complexing agent, wherein polymer

interacts with the complexing agent in a host-guest or a guest-host interaction to form an inclusion complex. And also composition can be used to deliver a therapeutic agent in the treatment of various disorders (see paragraph 0002). And also discloses suitable hosts which may be employed with the polymer include cavitands, crown ethers, cucurbiturils, calixarenes, cryptands and the like (see paragraph 0105), and therapeutic agents such as antibiotics, steroids, polynucleotides, plasmids, peptides, natural products and other biologically active macromolecules such as proteins and enzymes (see paragraph 0110).

When these references are taken together, one would have been motivated to extend Kim's teaching to add additional biodegradable polymers such as PGLA, PEG, cellulose derivatives, albumin, gelatin, alginate to maximize therapeutic efficacy. As suggested by cited references, one would have reasonably expected successful addition of biodegradable polymers because the effectiveness, extra benefits (facilities its clinical use and aid in the diagnosis before and after the treatment and further for the treatment of inherited or acquired disorders such as for e.g. cystic fibrosis, Gaucher's disease, muscular dystrophy, AIDS, cancers and neurological conditions is possible and thus the therapeutic effect on said disorders can be enhanced) and safety are already well proven and are well suggested by latter reference cited.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is

conventional knowledge or well within the skills of ordinary artisan as evidenced by these references cited.

Those of ordinary skill in the art would expect similar benefits from the instant composition of hydroxycucurbituril derivatives used as drug carriers, given the teachings of Kim in view of Pun. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01 (a).

Applicant's arguments filed on 11/13/2007 have fully considered but they are not persuasive.

Applicant asserts that Kim is completely silent as forming nanoparticles by the aggregation of a plurality of such cucurbitril derivatives.

Kim discloses the hydroxycucurbitril derivatives that can be used as a substitute for cyclodextrin, have cavities having a diameter of 4 to 15 angstroms (1.5 nm), which are able to include various compounds and derivatives therein (see page 17, lines 7-11).

Applicant further asserts that Pun dose not disclose nanoparticles in the composition.

Pun discloses a composition containing particulate composite of a polymer and a therapeutic agent. The particulate sizes may range from 50-1000 nm and the compositions are stable at physiological conditions allowing their use as delivery

vehicles for therapeutic agents and in the treatment of various diseases and disorders (see abstract and 0144).

Conclusion

1. No claims are allowed at this time.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAiR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 57i-272-1000

Jagadishwar R Samala
Examiner
Art Unit 1618

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600